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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,490	07/11/2000	Fearghus O'Foghludha	9105-21-IP	2050

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/31/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/614,490

Applicant(s)

O'FOGHLUDHA, FEARGHUS

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Response to Amendment

The amendment filed 9/30/2003 has been entered. The terminal disclaimer filed 9/30/2003 has been accepted.

Election/Restrictions

Newly submitted claims 10-19 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions I (claims 1-9) and I (claims 10-18) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed may be made by a materially different process, for example, the product of claim 1 contains a nuclide, a nuclide which is activated prior to or after formation of the claimed product would provide the same product. Also, the product of claim 19 is distinct from the originally claimed invention, in that it requires a specific combination of two different nuclides on the source. This is a distinct product since it contains two distinct radionuclides of a certain isotope. Note, the classification of radiohalogens has a different classification (424/1.85), as compared to phosphorus radionuclides (424/1.77) or metal radionuclides (424/1.65).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 10-19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

Any previous rejections that are not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Suthanthiran (US 5,163,896), for the reasons set forth in the office action mailed 5/30/2003.

Applicant's arguments filed 9/30/2203 have been fully considered but they are not persuasive.

Applicant asserts that Suthanthiran discloses products in which the nuclide is not part of the backbone of the polymer as claimed because the radioiodine is part of a pendent group.

This is not found persuasive because as stated in the previous office action, Suthanthiran discloses that the source can comprise P-32 polynucleotides, which are clearly a polymer having the nuclide as a constituent of the polymer backbone, as the P atom of a polynucleotide is in the chain or backbone of the polymer.

Applicant further asserts that Suthanthiran fails to disclose a nuclide that is activated by exposure of radiation.

This is not found persuasive as the above rejected claims are product claims and the above argument referring to "activated" is a method step. A radionuclide, which has been activated, is the same as a radionuclide. The claimed product is drawn to a source comprising a radionuclide, which is taught the prior art. Note, in product-by-process claims, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The fact the nuclide was made by a process of being "activated by exposure to radiation" would not give rise to a product which is different from Suthanthiran, since a radionuclide is a radionuclide, regardless of how it is obtained (however, most radionuclides are prepared by exposure to radiation).

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Claims 1, 3, 4 and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Grunze (US 2002/0054851), for the reasons set forth in the office action mailed 5/30/2003.

Applicant's arguments filed 9/30/2203 have been fully considered but they are not persuasive.

Applicant further asserts that Grunze fails to disclose a nuclide that is activated by exposure of radiation.

This is not found persuasive for the reasons set forth above, namely the claims are product claims and the above argument referring to "activated" is a method step. In product-by-process claims, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. Thus, the recitation of "activated by" cannot be used to differentiate over the cited art, as this is clearly a product-by-process limitation.

Applicant asserts that the polymer of Grunze is applied as a coating.

It is unclear how this argument is being used to differentiate over Grunze. The instant claims do not exclude such coatings. Grunze is drawn to radioactive devices, including stents, implants, etc., which is clearly within the scope of, at least, "test objects, rectangular and disc shaped sources configured to radiate an area, radioactive enclosures" as claimed. Also, these are more intended uses of the claimed source. The source as claimed requires a polymer and a nuclide (radionuclide) which is part of the backbone of the polymer. This is specifically disclosed by Grunze.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1 and 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Suthanthiran (US 5,163,896) or Grunze (US 2002/0054851) in view of either one of Park (US 6,152,869) or Good (US 5,342,283), for the reasons set forth in the office action mailed 5/30/2003.

Applicant's arguments filed 9/30/2203 have been fully considered but they are not persuasive.

Applicant asserts that nothing in Park or Good suggests that post-irradiation could be successful to irradiate a nuclide that is a chemically bound constituent of the polymer backbone.

This is not found persuasive. The advantage disclosed by Park and Good is using a stable nuclide, which may later be irradiated to provide a radionuclide. This advantage would not be dependent on the position of the nuclide, for example, whether or not it was in the backbone or elsewhere in the radioactive source. Obviousness does not require absolute predictability. The predictability of irradiating a nuclide to form radionuclide would be predictable to gain the advantage of Park and Good regardless of the position of the nuclide, as Park and Good do not suggest that the position of the nuclide is critical in irradiation. Further, the above claims are product claims. Thus, these claims do not require the actual steps that the source be formed and then irradiated. The only requirement is that a nuclide be activated. Park and Good clearly teach that nuclides which are activated into radionuclides may be used for such radioactive sources, such as, those disclosed by Suthanthiran or Grunze.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

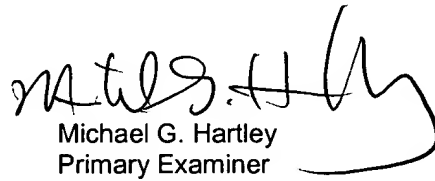
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1616

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